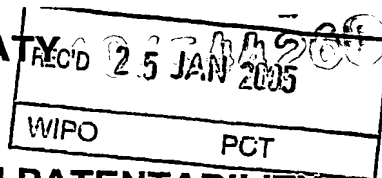




## PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference PA 5076 PCT/INT		<b>FOR FURTHER ACTION</b> See Form PCT/PEA/416	
International application No. PCT/GB2004/000406		International filing date (day/month/year) 03.02.2004	Priority date (day/month/year) 03.02.2003
International Patent Classification (IPC) or national classification and IPC A61B17/16			
Applicant UNIVERSITY COLLEGE LONDON et al.			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau) a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input checked="" type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 18.06.2004		Date of completion of this report 24.01.2005	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer Hamann, J Telephone No. +49 89 2399-7046 	

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/GB2004/000406

**Box No. I Basis of the report**

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
  - ☐ This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
    - ☐ international search (under Rules 12.3 and 23.1(b))
    - ☐ publication of the international application (under Rule 12.4)
    - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

**Description, Pages**

1-9  
as originally filed

**Claims, Numbers**

1-13  
as originally filed

**Drawings, Sheets**

1/3-3/3  
as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
    - ☐ the description, pages
    - ☐ the claims, Nos.
    - ☐ the drawings, sheets/figs
    - ☐ the sequence listing (*specify*):
    - ☐ any table(s) related to sequence listing (*specify*):
  4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
    - ☐ the description, pages
    - ☐ the claims, Nos.
    - ☐ the drawings, sheets/figs
    - ☐ the sequence listing (*specify*):
    - ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/GB2004/000406

**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:
- ☐ the entire international application,
  - ☒ claims Nos. 10-12  
because:
    - ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):
    - ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
    - ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
  - ☒ no international search report has been established for the said claims Nos. 10-12
  - ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
    - the written form ☐ has not been furnished
    - ☐ does not comply with the standard
    - the computer readable form ☐ has not been furnished
    - ☐ does not comply with the standard
  - ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
  - ☐ See separate sheet for further details

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/GB2004/000406

**Box No. IV Lack of unity of invention**

1. ☒ In response to the invitation to restrict or pay additional fees, the applicant has:
- ☐ restricted the claims.
  - ☒ paid additional fees.
  - ☐ paid additional fees under protest.
  - ☐ neither restricted nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.
  - ☒ not complied with for the following reasons:  
**see separate sheet**
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
  - ☒ the parts relating to claims Nos. 1-9,13 .

**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	4,5,7,13
	No: Claims	1-3,6,8,9
Inventive step (IS)	Yes: Claims	13
	No: Claims	1-9
Industrial applicability (IA)	Yes: Claims	1-9,13
	No: Claims	

2. Citations and explanations (Rule 70.7):

**see separate sheet**

**Re Item IV**

**Lack of unity of invention**

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

**1. Claims: 1-9**

A surgical kit for hip replacement comprising:  
a prosthetic femoral head and a reamer,  
the radius of curvature of the cutting envelope of the  
reamer being at most approximately 5 mm greater than that of  
the femoral head.

**2. Claim : 13**

A modular shell reamer for joint refurbishment of a ball and  
socket anatomical joint,  
having a shaft and a head separable from the shaft but  
capable of being securely coupled to the shaft in situ for  
use,  
the reamer head having reamer teeth facing not only  
outwardly toward the socket surface in use but also inwardly  
toward the ball surface.

**Problems to be solved:**

Invention 1: reaming a socket into an acetabulum until the cancellous  
bone is exposed, of a size and shape such that the prosthetic femoral  
head can be fitted closely and directly into the reamed acetabulum.

Invention 2: refurbishing a ball and socket anatomical joint such as a  
hip joint, without removing the femoral head.

The common concepts linking the two inventions are:

A reamer for reaming an acetabulum.

The combination of these concepts is not new in the sense of Article  
33(2) PCT; see e.g. the reamer of Figs. 15-20 in US-A-2,785,673.

Since the combination of the concepts shared by these inventions is not new and the problems to be solved by the inventions are technically unrelated (see above), there is no technical relationship among the inventions involving one or more of the same or corresponding special technical features in the sense of Article 13.2 PCT. Therefore, these inventions are not so linked as to form a single general inventive concept. Hence, the application lacks unity within the meaning of Rule 13.1 PCT.

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Reference is made to the following documents:  
D1: US-A-2,785,673 (ROGER ANDERSON) 19 March 1957 (1957-03-19)  
D2: US-A-5,895,375 (CHERVITZ ALAN ET AL) 20 April 1999 (1999-04-20)  
D3: US-A-6,231,611 (MOSSERI RAPHAEL) 15 May 2001 (2001-05-15)
2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claims 1-3, 6, 8, and 9** is **not new** in the sense of Article 33(2) PCT:

**Claim 9:**

The document **D1** discloses (the references in parentheses applying to this document) a prosthetic femoral head (39) and a reamer (51) according to claim 9. Since this reamer is used for "providing a socket in a pelvic bone for reception therein of a femoral head prosthesis" (column 9, lines 66-68), its radius of curvature is less than 5 mm greater than that of the femoral head.

**Claims 1-3, 6, and 8:**

Since it is not clear which structural limitations are implied by the features of these claims, these features are disregarded.

3. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of dependent **claims 4, 5, and 7** does **not involve an**

**inventive step** in the sense of Article 33(3) PCT:

**Claim 4:** membrane known from D2 (see 54 in Figs. 6 and 7)

**Claim 5:** see column 7, line 36 of D2 ("biodegradable")

**Claim 7:** see column 1, line 41 of D2 ("deliver local growth factors")

4. **Claim 13:**

4.1 The closest prior art may be seen to be either the femoral reamer shown in Figs. 1-5 of D3, or the acetabular reamer shown in Figs. 6-8 of D3.

Both devices are modular shell reamers for joint refurbishment of a ball and socket anatomical joint such as a hip joint, having a shaft and a substantially part-spherical head separable from the shaft but capable of being securely coupled to the shaft in situ for use, the reamer head having reamer cutting teeth facing **either** outwardly toward the socket surface (in case of the acetabular reamer) **or** inwardly toward the ball surface (in case of the femoral reamer).

4.2 The subject-matter of claim 13 differs from these devices in that the reamer head has reamer cutting teeth facing **not only** outwardly toward the socket surface in use **but also** inwardly toward the ball surface.

4.3 This has the advantages that the femoral head and acetabular surfaces can be reamed in a single operation and that the resulting surfaces are fitting with each other.

4.4 From the available prior art it is neither known nor rendered obvious to combine a femoral reamer and an acetabular reamer in the way defined in claim 13.